



General

Guideline Title

Clinical practice guideline: tonsillectomy in children.

Bibliographic Source(s)

Baugh RF, Archer SM, Mitchell RB, Rosenfeld RM, Amin R, Burns JJ, Darrow DH, Giordano T, Litman RS, Li KK, Mannix ME, Schwartz RH, Setzen G, Wald ER, Wall E, Sandberg G, Patel MM, American Academy of Otolaryngology-Head and Neck Surgery Foundation. Clinical practice guideline: tonsillectomy in children. Otolaryngol Head Neck Surg. 2011 Jan;144(1 Suppl):S1-30. [229 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, and Option) are defined at the end of the "Major Recommendations" field.

Statement 1. Watchful Waiting for Recurrent Throat Infection

Clinicians should recommend watchful waiting for recurrent throat infection if there have been fewer than 7 episodes in the past year or fewer than

5 episodes per year in the past 2 years or fewer than 3 episodes per year in the past 3 years.

<u>Recommendation</u> based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade B, randomized controlled trials with minor limitations that fail to show clinically important advantages of surgery over observation alone (as stated in Statement 1), and Grade C, observational studies showing improvement with watchful waiting
- Benefit: Avoid unnecessary surgery with potential complications of vomiting, hemorrhage, pain, infection, or anesthesia problems
- Harm: Waiting may result in delayed treatment in patients who have unusually frequent and severe recurrent throat infections
- Cost: Potential direct cost of managing future throat infections
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Panel consensus that tonsillectomy for recurrent throat infection should be limited to circumstances for which clinically
 important benefits are shown in randomized controlled trials; emphasis on avoiding harm related to surgery or anesthesia in a condition that
 may be largely self-limited
- Role of patient preferences: Limited to specific unusual circumstances such as complications of tonsillitis or comorbidities
- Intentional vagueness: None
- Exclusions: Patients with peritonsillar abscess, personal or family history of rheumatic heart disease, Lemierre syndrome, or severe infections requiring hospitalization
- Policy level: Recommendation

Statement 2. Recurrent Throat Infection with Documentation

Clinicians may recommend tonsillectomy for recurrent throat infection with a frequency of at least 7 episodes in the past year or at least 5 episodes per year for 2 years or at least 3 episodes per year for 3 years with documentation in the medical record for each episode of sore throat and one or more of the following: temperature >38.3°C, cervical adenopathy, tonsillar exudate, or positive test for Group A β -hemolytic streptococcus (GABHS).

Option based on systematic reviews and randomized controlled trials with minor limitations, with a balance between benefit and harm.

Evidence Profile

- Aggregate evidence quality: Grade B, well-designed randomized controlled trials with minor limitations; some Grade C observational studies
- Benefit: Modest reduction in the frequency and severity of recurrent throat infection for up to 2 years after surgery; modest reduction in frequency of group A streptococcal infection for up to 2 years after surgery; improved disease-specific quality of life (QoL)
- Harm: Risk and morbidity of tonsillectomy in patients appropriately selected for the procedure, including, but not limited to, persistence of throat infection, pain, and missed activity after surgery, hemorrhage, dehydration, injury, and anesthetic complications
- Cost: Direct cost of tonsillectomy; direct nonsurgical costs (antibiotics, clinician visit) and indirect costs (caregiver time, time missed from school) associated with recurrent infection
- Benefits-harm assessment: Balance between benefit and harm
- Value judgments: Importance of balancing the modest, short-term benefits of tonsillectomy in carefully selected children with recurrent throat
 infection against the favorable natural history seen in control groups and the potential for harm or adverse events, which, although infrequent,
 may be severe or life-threatening
- Role of patient preferences: Large role for shared decision making in severely affected patients, given favorable natural history of recurrent throat infections and modest improvement associated with surgery; limited role in patients who do not meet strict indications for surgery
- Intentional vagueness: None
- Exclusions: None
- Policy level: Option

Statement 3. Tonsillectomy for Recurrent Infection with Modifying Factors

Clinicians should assess the child with recurrent throat infection who does not meet criteria in Statement 2 for modifying factors that may nonetheless favor tonsillectomy, which may include but are not limited to multiple antibiotic allergy/intolerance, PFAPA (periodic fever, aphthous stomatitis, pharyngitis, and adenitis), or history of peritonsillar abscess.

<u>Recommendation</u> based on randomized controlled trials and observational studies with a preponderance of benefit over harm.

- Aggregate evidence quality: Grade B, randomized controlled trials with limitations, for PFAPA; Grade C, observational studies for all other factors
- Benefit: Identifying factors that might otherwise have been overlooked, which may influence the decision to perform tonsillectomy and ultimately improve patient outcomes
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Role of patient preferences: Should be included
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

Statement 4. Tonsillectomy for Sleep-disordered Breathing (SDB)

Clinicians should ask caregivers of children with SDB and tonsil hypertrophy about comorbid conditions that might improve after tonsillectomy, including growth retardation, poor school performance, enuresis, and behavioral problems.

Recommendation based on observational before-and-after studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade C, before-and after observational studies
- Benefit: To improve decision making in children with SDB by identifying comorbid conditions associated with SDB, which might otherwise
 have been overlooked, and may improve after tonsillectomy
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception that potentially important comorbid conditions may be overlooked or not included in routine assessment of
 children with SDB, even though they may improve after intervention; consensus that substantial evidence from before-and after studies
 supports inquiring about these conditions, despite an absence of randomized controlled trials supporting a recommendation for or against
 tonsillectomy.
- Role of patient preferences: Large role for caregiver education and shared decision making
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

Statement 5. Tonsillectomy and Polysomnography (PSG)

Clinicians should counsel caregivers about tonsillectomy as a means to improve health in children with abnormal PSG who also have tonsil hypertrophy and SDB.

Recommendation based on observational before-and-after studies with a preponderance of benefit over harm.

Evidence Profile: Tonsillectomy and PSG

- Aggregate evidence quality: Grade C, observational, before-and-after studies and meta-analysis of observational studies showing substantial
 reduction in the prevalence of SDB and abnormal PSG after tonsillectomy
- Benefit: Improved caregiver awareness of how tonsillectomy may benefit their child when PSG is abnormal, including improved sleep, better
 nighttime and daytime functioning, improved functional health status, and prevention or improvement of comorbid conditions, including
 growth retardation, poor school performance, enuresis, and behavioral problems
- Harm: Potential anxiety to caregivers from counseling
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Panel consensus that objectively documented SDB with PSG may warrant intervention, even if not associated with
 comorbid conditions; recognition that abnormal PSG results encompass a broad range of values, with lack of evidence to support definitions
 of severity that correlate with surgical outcomes; concern that not treating children with abnormal PSG may lead to future morbidity or

- impaired health status
- · Role of patient preferences: Moderate; different caregivers may seek different levels of information and detail
- Intentional vagueness: The panel uses the term *abnormal PSG* recognizing there is no consensus among clinicians, institutions, or disciplines regarding the exact criteria that define an abnormal study. The panel agreed that indications for PSG are an important area for clarification, but it was deemed beyond the guideline scope and excluded from discussion
- Exclusions: None for counseling
- Policy level: Recommendation

Statement 6. Outcome Assessment for SDB

Clinicians should counsel caregivers and explain that SDB may persist or recur after tonsillectomy and may require further management.

<u>Recommendation</u> based on observational studies, case-control and cohort design, with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade C, before-and-after observational studies and systematic reviews
- Benefit: Identify children who require further management of SDB; improve outcomes
- Harm: None
- Cost: Time spent in counseling
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception of inadequate counseling by physicians and underappreciation that SDB may persist or recur despite tonsillectomy
- Role of patient preferences: Limited
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

Statement 7. Intraoperative Steroids

Clinicians should administer a single, intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.

<u>Strong recommendation</u> based on randomized controlled trials and systematic reviews of randomized controlled trials with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade A, randomized controlled trials and multiple systematic reviews, for preventing postoperative nausea and vomiting (PONV); Grade A, randomized controlled trials and 1 systematic review, for decreased pain and shorter times to oral intake
- Benefit: Decreased incidence of PONV up to 24 hours post-tonsillectomy, decreased times to first oral intake, and decreased pain as measured by lower pain scores and longer latency times to analgesic administration
- Harm: No adverse events in all randomized controlled trials except one, which reported increased hemorrhage as a secondary outcome unadjusted for other risk factors
- Cost: Direct cost of medication and indirect costs of drug administration
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Decreased PONV and postoperative pain likely to result in increased patient satisfaction and decreased incidence of
 overnight hospital admission, associated with lower total health care costs compared with direct and indirect costs of drug administration
- Role of patient preferences: None
- Intentional vagueness: None
- Exclusions: Patients with endocrine disorders who are already receiving exogenous steroids or in whom steroid administration may interfere with normal glucose-insulin regulation (e.g., diabetics)
- Policy level: Strong recommendation

Statement 8. Perioperative Antibiotics

Clinicians should not routinely administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.

<u>Strong recommendation</u> against administering or prescribing based on randomized controlled trials and systematic reviews with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade A, randomized controlled trials and systematic reviews, showing no benefit in using perioperative antibiotics to reduce post-tonsillectomy morbidity
- Benefit: Avoidance of adverse events related to antimicrobial therapy, including rash, allergy, gastrointestinal upset, and induced bacterial resistance
- Harm: None
- Cost: None
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Although the panel recognizes that antimicrobial therapy is often used in perioperative management, this practice is suboptimal given the lack of demonstrable benefits in randomized controlled trials plus the well-documented potential adverse events and cost of therapy
- Role of patient preferences: None
- Intentional vagueness: The panel advises against routine antimicrobial therapy, recognizing that there may be individual circumstances in
 which use of antimicrobials for a given patient is deemed appropriate by the clinician
- Exclusions: Patients with cardiac conditions requiring perioperative antibiotics for prophylaxis against bacterial endocarditis or implants; patients undergoing tonsillectomy with concurrent peritonsillar abscess
- Policy level: Strong recommendation against

Statement 9. Postoperative Pain Control

The clinician should advocate for pain management after tonsillectomy and educate caregivers about the importance of managing and reassessing pain.

<u>Recommendation</u> based on randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade B, randomized controlled trials comparing analgesics after tonsillectomy, and Grade C, observational studies suggesting inadequate pain control and hydration after tonsillectomy
- · Benefit: Pain relief, improved and faster recovery; avoidance of complications from dehydration, inadequate food intake
- Harm: Adverse effects of specific analgesic preparations
- Cost: Time spent by clinician advocating; direct cost of medications used
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perception by the panel that pain control is often underemphasized and inadequately discussed after tonsillectomy;
 importance of engaging the caregiver and providing education about pain management and reassessment
- · Role of patient preferences: Limited regarding advocacy; substantial role in choice of analgesic and method of reassessment
- Intentional vagueness: None
- Exclusions: None
- Policy level: Recommendation

Statement 10. Post-tonsillectomy Hemorrhage

Clinicians who perform tonsillectomy should determine their rate of primary and secondary post-tonsillectomy hemorrhage at least annually.

<u>Recommendation</u> based on observational studies with a preponderance of benefit over harm.

Evidence Profile

- Aggregate evidence quality: Grade C, observational studies and large-scale audit, showing variability in postoperative hemorrhage rates and some association with surgical technique; Grade C, observational studies, showing hemorrhage as a consistent sequela of tonsillectomy with heterogeneity among studies
- Benefit: Improve preoperative counseling for tonsillectomy; encourage quality improvement efforts
- Harm: None
- Cost: Administrative burden
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Perceived heterogeneity among clinicians regarding knowledge of their own hemorrhage rates after tonsillectomy; potential

for clinicians to reassess their process of care and improve quality

- Role of patient preferences: Limited
- Intentional vagueness: Specifics of how to determine the hemorrhage rate are left to the clinician
- Exclusions: None
- Policy level: Recommendation

Definitions:

Guideline Definitions for Evidence-Based Statements

Strong recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D) or that well-done studies (Grade A, B, or C) show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No recommendation: No recommendation means there is both a lack of pertinent evidence (Grade D) and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Evidence Quality for Grades of Evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Case reports, reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Recurrent throat infections and/or sleep-disordered breathing for which tonsillectomy is indicated

Guideline Category

Counseling

Evaluation

Anesthesiology
Family Practice
Infectious Diseases
Internal Medicine
Otolaryngology
Pediatrics
Sleep Medicine
Surgery
Intended Users
Advanced Practice Nurses
Hospitals
Physician Assistants
Physicians
Guideline Objective(s)
 To provide clinicians with evidence-based guidance in identifying children who are the best candidates for tonsillectomy To optimize the perioperative management of children undergoing tonsillectomy To emphasize the need for evaluation and intervention in special populations To improve counseling and education of families of children who are considering tonsillectomy for their child To highlight the management options for patients with modifying factors

Target Population

Management

Clinical Specialty

Treatment

Children 1 to 18 years old under consideration for tonsillectomy

• To reduce inappropriate or unnecessary variations in care

Note: The guideline does not apply to populations of children excluded from most tonsillectomy research studies, including those with diabetes mellitus, cardiopulmonary disease, craniofacial disorders, congenital anomalies of the head and neck region, sickle cell disease, and other coagulopathies or immunodeficiency disorders.

Interventions and Practices Considered

Counseling/Evaluation

- 1. Educating caregivers about tonsillectomy as a means to improve health in children with abnormal polysomnography who also have tonsil hypertrophy and sleep-disordered breathing (SDB)
- 2. Educating caregivers regarding postoperative SDB

- 3. "Watchful waiting" for recurrent throat infection based on number of episodes of infection
- 4. Assessing child for modifying factors favoring tonsillectomy
- 5. Documentation of comorbid conditions in children with SDB and tonsil hypertrophy

Treatment/Management

- 1. Tonsillectomy for children with recurrent infection that meets criteria for frequency, severity, treatment, and documentation of illness
- 2. Use of single intraoperative dose of dexamethasone
- 3. Use of perioperative antibiotics (recommendation against routine use)
- 4. Postoperative pain management (providing information, prescribing, educating caregivers about pain relief)
- 5. Documentation of rate of post-tonsillectomy hemorrhage

Major Outcomes Considered

- Frequency and severity of throat infection
- · Quality of life
- Functional and behavioral outcomes in children with sleep-disordered breathing
- Morbidity of tonsillectomy
- Incidence of postoperative nausea and vomiting
- Pain relief, recovery rate, and rate of complications from dehydration or inadequate food intake
- · Rates of primary and secondary hemorrhage following tonsillectomy

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

The systematic literature search was divided into 2 stages and aimed to identify clinical practice guidelines, systematic reviews, or meta-analyses (stage I) and randomized controlled trials (stage II) using key biomedical literature databases (see Table 1 in the original guideline document). The search was based on the string tonsillectom*, adenotonsillectom*, tonsillotom*, posttonsillectom*, (tonsil* OR adenotonsil*) AND (surg* OR operat* OR preop* OR periop* OR postop*). Results were screened to remove duplicates and citations that were not pertinent.

- 1. Published and unpublished consensus- and evidence-based clinical practice guidelines less than 10 years old in English met inclusion criteria. The final data set included 17 guidelines, and of those, 2 guidelines met quality criteria of having been produced under the auspices of a medical association or organization and having an explicit, a priori, method for ranking evidence and linking evidence to recommendations.
- 2. Systematic reviews less than 15 years and meta-analyses with a systematic review in English met inclusion criteria. The search filter used to identify systematic reviews in PubMed was devised based on the search strategy used by the National Health Service Evidence—Cancer. Reviews that met a rating of adequate required a clear objective, explicit search strategy, and valid data extraction. The final data set included 36 systematic reviews (including 9 Cochrane systematic reviews).
- 3. Randomized controlled trials published in English with no age restrictions were identified using an adaptation of the Cochrane Highly Sensitive Search Strategy. Published or unpublished completed trials with a definite or possible randomized controlled design met inclusion criteria. The final data set yielded 705 studies that were grouped into the following broad topics: analgesia (193), technique (125), anesthesia (67), nausea/vomiting (62), hemostasis (45), recovery (35), steroids (26), surgical indications (24), antibiotics (16), outcomes assessment (15), surgical complications (2), perioperative care (2), and other (93).

Results of the literature searches were distributed to guideline panel members at the first meeting, including electronic listings with abstracts (if available) of the searches for guidelines, randomized controlled trials, and systematic reviews. This material was supplemented, as needed, with targeted systematic searches to address specific needs identified in developing the guideline through April 11, 2010.

Number of Source Documents

- 17 guidelines
- 36 systematic reviews
- 705 studies

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case control and cohort design)

Grade D: Case reports, reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized, and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in "Ratings Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The guideline panel was chosen to represent fields of sleep medicine, advanced practice nursing, anesthesiology, infectious disease, family medicine, otolaryngology—head and neck surgery, pediatrics, and consumers. Several group members had prior experience in developing clinical practice guidelines.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 9 months devoted to guideline development ending in 2010, the group met twice with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

The Guideline Implementability Appraisal and Extractor tool was used to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in May 2010 and modified an advanced draft of the guideline.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C)*. In some clearly identified circumstances, recommendations may be made on the basis of lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*Refer to "Rating Scheme for the Strength of the Evidence" field for the definitions of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final draft guideline was distributed to a multidisciplinary group of 44 external reviewers, representing the target audience, for feedback and comment. Responses were compiled, reviewed by a subgroup of the panel, and incorporated into the guideline. The document was then submitted to the journal's peer-review process before publication.

The recommendations were also compared with guidelines for tonsillectomy from the Italian National Program Guidelines and the Scottish Intercollegiate Guidelines Network (see Table 9 in the original guideline document for a detailed comparison).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

The recommendations contained in the practice guideline are based on the best available published data through April 11, 2010. Where data were lacking, a combination of clinical experience and expert consensus was used.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Tonsillectomy may improve quality of life (QoL) by reducing throat infections, health care provider visits, and the need for antibiotic therapy. Similarly, sleep disordered breathing (SDB) is associated with cognitive and behavioral impairment in children that usually improves after tonsillectomy along with QoL, sleep disturbance, and vocal quality.

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- Tonsillectomy is a surgical procedure with an associated morbidity that includes possible hospitalization, risks of anesthesia, prolonged throat pain, and financial costs.
- A common complication of tonsillectomy is bleeding during or after the surgery. In published reports, the rate of primary hemorrhage (within 24 hours of surgery) has ranged from 0.2% to 2.2% and the rate of secondary hemorrhage (more than 24 hours after surgery) from 0.1% to 3%. Hemorrhage after tonsillectomy may result in readmission for observation or in further surgery to control bleeding.
- Operative complications of tonsillectomy include trauma to the teeth, larynx, pharyngeal wall, or soft palate; difficult intubation; laryngospasm; laryngeal edema; aspiration; respiratory compromise; endotracheal tube ignition; and cardiac arrest. Injury to nearby structures has been reported, including lip burn, eye injury, and fracture of the mandibular condyle.
- Postoperative complications of tonsillectomy include nausea, vomiting, pain, dehydration, referred otalgia, postobstructive pulmonary
 edema, velopharyngeal insufficiency, and nasopharyngeal stenosis. Complications are more common in patients with craniofacial disorders,
 Down syndrome, cerebral palsy, major heart disease, or bleeding diatheses and in children younger than 3 years with polysomnography
 (PSG)-proven obstructive sleep apnea (OSA).
- After tonsillectomy, about 1.3% of patients experience delayed discharge during the initial hospital stay, and up to 3.9% have secondary
 complications requiring readmission. The primary reasons for readmission or prolonged initial stay included pain, vomiting, fever, and
 tonsillar hemorrhage.
- Many unusual and rare complications of tonsillectomy have been described. Among these are reports of vascular injury, subcutaneous
 emphysema, jugular vein thrombosis, atlantoaxial subluxation (Grisel syndrome), taste disorders (hypogeusia, ageusia, dysgeusia, and
 phantogeusia), and persistent neck pain (Eagle syndrome).
- There are no current estimates of tonsillectomy mortality, but a prospective audit reported only one postoperative death after 33,921
 procedures in England and Northern Ireland. About one-third of deaths are attributable to bleeding, while the remainder are related to
 aspiration, cardiopulmonary failure, electrolyte imbalance, or anesthetic complications. Similarly, airway compromise is the major cause of
 death or major injury in malpractice claims after tonsillectomy.

For additional harms associated with specific interventions considered in the guideline, see the "Major Recommendations" field.

Qualifying Statements

Qualifying Statements

This clinical practice guideline is not intended as a sole source of guidance in managing children who are candidates for tonsillectomy.
 Rather, it is designed to assist clinicians by providing an evidence based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate

- approach to managing this problem.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- This guideline is intended to focus on quality improvement opportunities judged most important by the working group. It is not intended to
 be a comprehensive, general guide for managing patients undergoing tonsillectomy. In this context, the purpose is to define useful actions for
 clinicians, regardless of discipline, to improve the quality of care. Conversely, the statements in this guideline are not intended to limit or
 restrict care provided by clinicians based on the assessment of individual patients.

Implementation of the Guideline

Description of Implementation Strategy

The panel identified several potential areas of the guideline in which obstacles to implementation might occur based on current practice patterns. Clinicians may be unfamiliar with the Paradise criteria for tonsillectomy, having relied on less stringent personal or organizational criteria to identify surgical candidates. Moreover, the importance of concurrent documentation to support the medical history is not always appreciated. Overcoming these beliefs will require teaching materials plus integration of this knowledge into existing continuing medical education venues for clinicians who assess tonsillectomy candidacy. Educational material will also be needed for caregivers of children with recurrent throat infection to explain the rationale for watchful waiting instead of earlier surgical intervention.

Antibiotics are commonly used in the routine, perioperative care of children having tonsillectomy, despite convincing evidence of no beneficial impact on recovery (except for possibly reduced fever). Changing this behavior will require a paradigm shift, which is likely to be met with resistance based on long-established practices and anecdotal perceptions as to why antibiotics may be beneficial. Similarly, nonsteroidal anti-inflammatory drugs (NSAIDs) are used infrequently for pain control based on unfounded concerns about increased postoperative hemorrhage, which are not supported by systematic reviews of randomized trials. Conversely, codeine is often used after tonsillectomy despite no benefit over acetaminophen in randomized controlled trials plus a known adverse event profile that includes nausea and vomiting. Educational materials and brochures will be needed to reduce perioperative antibiotics, promote NSAIDs for pain control, and avoid codeine as a routine addition to acetaminophen.

Several of the guideline recommendations deal with advocacy, education, or counseling. The panel opted for this approach, instead of recommending specific drugs or interventions, because in many cases high-quality, consistent evidence was lacking. Relevant statements in the guideline deal with managing the child with an abnormal polysomnography (PSG), anticipating possible persistence of sleep-disordered breathing and abnormal PSG after tonsillectomy, and involving the caregiver in postoperative pain management. Appropriate education materials and brochures will be needed to efficiently implement these strategies at the point of care.

The guideline statement on post-tonsillectomy hemorrhage requests that clinicians who perform tonsillectomy determine their rate of primary and secondary post-tonsillectomy hemorrhage at least annually. Existing information systems at some hospitals or surgicenters may allow this to be readily accomplished, but for others, there will be an administrative burden in acquiring these data. This barrier to implementation suggests the need for a tool or data form to assist clinicians in gathering the relevant data.

Implementation Tools

Patient Resources

Resources

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Baugh RF, Archer SM, Mitchell RB, Rosenfeld RM, Amin R, Burns JJ, Darrow DH, Giordano T, Litman RS, Li KK, Mannix ME, Schwartz RH, Setzen G, Wald ER, Wall E, Sandberg G, Patel MM, American Academy of Otolaryngology-Head and Neck Surgery Foundation. Clinical practice guideline: tonsillectomy in children. Otolaryngol Head Neck Surg. 2011 Jan;144(1 Suppl):S1-30. [229 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jan

Guideline Developer(s)

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Guideline Committee

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Foundation Guideline Development Panel

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) Foundation. Potential conflicts of interest for all panel members were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they: (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Raouf S. Amin, grant: Proctor and Gamble; Eric Wall, consultant: Anthem/Wellpoint (low-back pain pilot guideline), Senior Medical Director: Qualis Health

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Availa	able in Portable Docume	nt Format (PDF) from ti	ne American Academy (of Otolaryngology—Head a	and Neck Surgery
Foundation Web site					

Availability of Companion Documents

lownload from the SAGE Journals Online Web site

Patient Resources

The following are available:

• What to expect after your child has tonsillectomy/adenoidectomy surgery. Fact sheet. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNS). 2 p. Electronic copies: Available in Portable Document Format (PDF) from the AAO-HNS Web site

•	Tonsillectomy procedures. Fact sheet. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation
	(AAO-HNS). Electronic copies: Available from the AAO-HNS Web site
•	Member expert Q & A: post-tonsillectomy pain management. Alexandria (VA): American Academy of Otolaryngology-Head and Neck
	Surgery Foundation (AAO-HNS). Electronic copies: Available from the AAO-HNS Web site

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NGC Status

This NGC summary was completed by ECRI Institute on March 14, 2011. The information was verified by the guideline developer on April 25, 2011. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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